EXHIBIT A

CLINICAL ARTICLES

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The Use of Drains in Oral and Maxillofacial Surgery:

A Review and a New Approach

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The use of drains in oral and maxillofacial surgery is reviewed and discussed. Their relative advantages and disadvantages and potential complications are explained, and principles for wound drainage are developed. Use of the Jackson-Pratt drainage system, a versatile type of suction that minimizes the complications associated with wound drainage, is described.

Placement of surgical drains, both intraorally and extraorally, is a common technique of oral and maxillofacial surgery. Drains are used to evacuate pus, pooled blood, or serum from wounds, as well as to eliminate potential dead tissue space. The purpose of this report is to discuss the use of drains in modern surgical practice and subsequently to describe the use of the Jackson-Pratt drainage system in oral and maxillofacial surgery.

Classes of Drains

There are three classes of drains commonly used in oral and maxillofacial surgery today: gauze drains, simple rubber drains, and suction drains. Gauze drains, whether or not they are treated with antiseptics such as iodoform, promote clotting of blood and plasma. They often, therefore, act as plugs rather than as drains, and their use as a drain is generally not recommended.

There are many types of simple rubber drains; examples are Foley catheters, red rubber French catheters, tubular "cigarette" drains, rubber dam material, and the widely accepted latex Penrose drains. The simple rubber drain has been used with varying degrees of success for the evacuation of pooled blood or infected material from, or the elimination of dead space in, wounds. These drains are adaptable, soft, and inexpensive. They function primarily by maintaining the patency of the wound and by providing a channel for the movement of pus or blood by gravity or pressure. Rubber drains do not prevent clotting, do not (except catheter-type drains) facilitate irrigation by maintaining a patent internal lumen, and do not allow suction to be applied to the wound. Furthermore, any external drainage must be absorbed into a dressing. Bulky external dressings may hold infected material, blood, or transudates against the edges of the wound. This places potential pathogens and their substrates against the weakest point in the body's defenses, the incision line, and the use of dressings for clean wounds is therefore discouraged.

A drain to which suction can be applied can eliminate pooled blood, serum, and dead space from a wound by drawing the separated tissue surfaces together.[1] The type of suction drain most frequently used in oral and maxillofacial surgery is the polyethylene Snyder Hemovac® drain.[2,3] Other brands of suction drains are also available, such as the Argyle Suction Set® and Davol Reliavac®.[3]

The Hemovac drain consists of a perforated polyethylene tube with a radiopaque marker. The tube can be attached to a compressible vacuum-generating device into which evacuated material is drawn. Since all aspirated fluids are maintained within a closed, previously sterile container, this is a closed-suction system, the maintenance of which depends on an airtight and water-tight seal at the incised wound and at the point where the drain leaves the body surface. If external venting of the tubing or other means for extraneous contamination is incorporated into the system, it becomes an open-suction system; these tend to become contaminated and

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even to cause wound infections.[4] Bacterial filters for vented suction systems are available, and they are reported to be effective.[5,6]

The Hemovac system has several advantages in addition to being a closed-suction system. It is available in several sizes. Since the aspirated material is contained within the suction reservoir, bulky absorptive dressings, which hold contaminated effluent against the wound, are avoided.[7] Reliable aerobic cultures, which may forecast infection, can be obtained from the apparatus.[8] However, a disadvantage of the Hemovac is that it is made of a rigid polyethylene material that can irritate or erode soft, pulsatile, or mobile vital structures.[9] The drain portals, and even the lumen, often become clogged with adjacent muscle, connective tissue, or necrotic debris. This has often been interpreted clinically as clotting of blood within the lumen.[10] Moreover, due to its physical design, the Hemovac system is not readily adaptable for irrigation of the wound if this is indicated.

Complications of Drainage

Complications of surgical wound drainage include tissue reaction to the drain material, irritation or erosion of adjacent structures, creation of dead space about the drain itself, and most significantly, potentiation of infection in clean wounds.

The presence of a drain can also stimulate a foreign-body reaction in the surrounding tissues. Some authors assert this may be due to the material from which the drain is constructed.[7,9] but an experimental study that compared drains made of silicone rubber and latex rubber found no significant difference in tissue reactions or infection rates.[11]

As previously mentioned, a rigid drain can damage nearby pulsatile vessels or glandular tissue, especially in freely mobile areas of the body.[1] A soft, supple drain, such as the Penrose or silicone rubber drain, is therefore recommended.[4,9,12,13] The shape of a drain is also important. A round drain creates an area of dead space around it as the separated soft tissue surfaces drape against it. This may become a point of collection for unwanted fluids and organisms and can therefore impede healing.[1,13] A flat drain minimizes this problem.

The most significant and frequent complication of wound drainage is the potentiation of infection by the drain itself.[4,14,15] The presence of a drain brought out through the cut edges of a wound has been shown to potentiate the development of infection in wounds containing a subinfective dose of bacteria.[11] Furthermore, the drain may provide a pathway for the migration of surface pathogens into the interior of a wound.[14] The presence of a drain seems to decrease the local resistance of wounds. A prospective study of 23,649 surgical wounds demonstrated a clean-wound infection rate for undrained wounds of 1.53%. This rate rose 57% (to 2.4%) when clean wounds are drained with a Penrose drain brought out through an adjacent stab wound and rose 161% (to 4%) when a Penrose drain was brought out through the wound itself. Interestingly, clean wounds treated with closed-suction drains became infected only 18% more frequently (1.8%) than undrained clean wounds.[15] As previously mentioned, vented suction drains (also called sump drains) tend to become infected via airborne bacteria unless a bacterial filter is used in the venting apparatus.[4-6]

Principles of Wound Drainage

In view of the necessity for, and complications of, wound drainage, rational indications must be developed for the use of drainage in oral and maxillofacial surgery. Halsted summarized the basic approach to drainage in 1898: "A drain produces invariably some necrosis of the tissues with which it comes in contact, and enfeebles the power of resistance of these tissues toward organisms. But given necrotic tissues plus infection, a drain becomes almost indispensable."[16]

When there is significant infection and suppuration, the indication for drainage is unquestioned. Dependent drainage via a simple rubber drain is adequate in most situations. However, when it is desirable to irrigate an abscess or an area of osteomyelitis, a noncollapsible type of drain should be used.

Because of the increased potential for infection, serious consideration must be given to the decision of whether to drain a clean wound. There are valid indications for doing so.

A drain may be placed in a clean wound to remove any blood that may collect after wound closure in areas of potentially inadequate hemostasis, such as when large areas of medullary bone are exposed in the sagittal split osteotomy[17] or in the donor site of an iliac crest bone graft. Drainage may also be justifiably used in a clean wound when there is a significant potential for the formation of dead space with resultant hematoma or seroma. A drain may serve to eliminate dead space under large flaps, after the removal of the submandibular gland, or after debridement of, or grafting to, the mandible.

In view of the available data on postoperative infection of drained clean wounds,[15] a closed-suction drain brought out through a separate stab incision should be used to eliminate hematoma and dead space from clean wounds. This procedure should

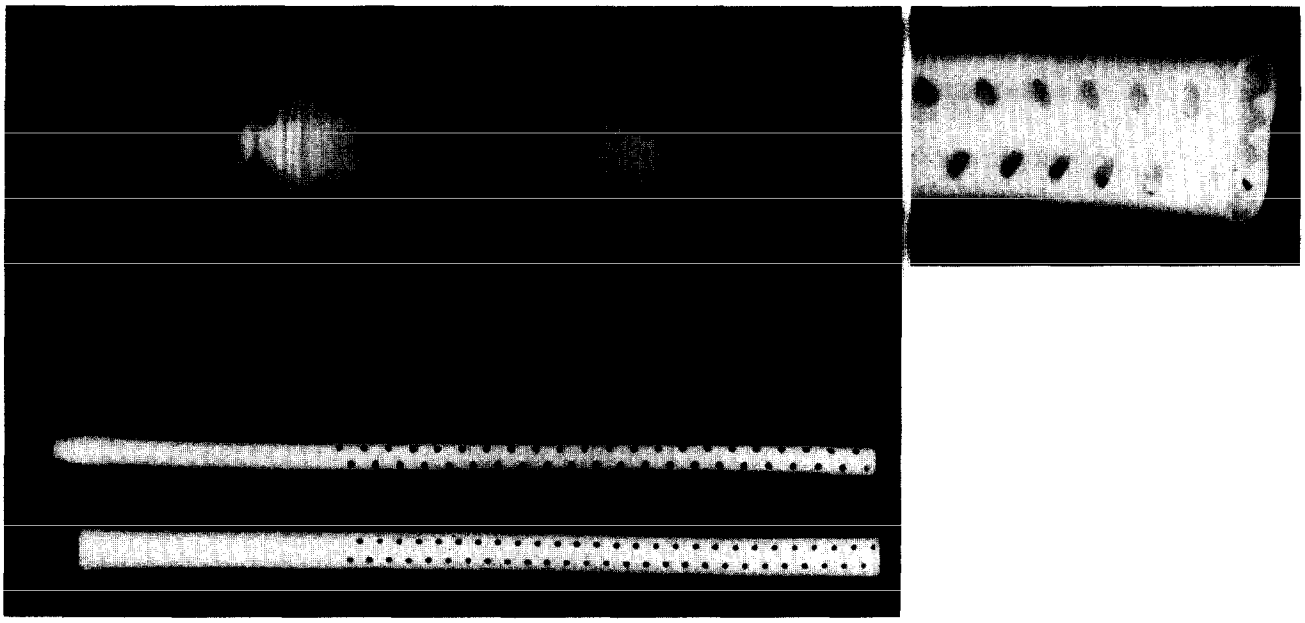

FIGURE 1. The Jackson-Pratt Drainage System. *Left,* from top to bottom, the 100-cc compressible suction reservoir, a 3.2-mm round drain, and the 7-mm and 10-mm flat drains. Note that the drains have standard connectors for syringes, which can be used for aspiration or irrigation. Other sizes of round drains, T-tubes, Y-connectors, and connectors for various sizes of tubing are also available. *Right,* a close-up view of the 10-mm, flat Jackson-Pratt drain. Note the perforations on both sides and the longitudinal internal ridges, which prevent collapse of the drain.

cause only a very small increase in the risk of infection.

In 1905 Yates stated, "When the discharge ceases it is time to discontinue drainage."[18] This statement holds true today. Hemostatic drains and drains for the obturation of dead space should be removed at 48 hours, or earlier if drainage becomes minimal.[1,9,13,19] Drainage of infected material should be maintained until suppuration is minimal; this occurs usually between two and seven days.

The Jackson-Pratt Drain System

In 1971 Frederick E. Jackson and Richard A. Pratt, III, introduced a silicone rubber (Silastic®) drain system for use in neurosurgery, primarily for evacuation of subdural hematomas.[9] The system has found use in general surgery for peritoneal drainage and to drain the bed of the gallbladder after cholecystectomy.[12] In head and neck surgery, the Jackson-Pratt system has been used after neck dissections, composite resections, temporal bone resections, and sialadenectomies.[13] We have used this system extensively in oral and maxillofacial surgery for drainage and irrigation of facial abscesses and osteomyelitis of the mandible, as well as for elimination of dead space and avoidance of hematoma.

The Jackson-Pratt drainage system consists of both flat and round perforated drains available in several lengths and diameters. The drain tubing is internally supported by longitudinal ridges to prevent collapse of the lumen if tension, pressure, or torsion is applied. The drains are made of high-tensile-strength silicone rubber into which a radiopaque strip is incorporated. Suction reservoirs, extension tubing, T-tubes, Y-connectors, and adapters are also available (Fig. 1).

The advantages of the silicone rubber construction of the Jackson-Pratt drain are that it resists intraluminal clotting, and because it is soft and supple, it does not cause erosion of pulsating vessels or compress nerves and veins. Its flat shape minimizes surrounding dead space. This apparatus can be used either as a closed-suction drainage system under large flaps or in dead space, or as an irrigating drain in cases of osteomyelitis or abscess. When the suction-generating reservoir is used, reliable aerobic cultures can be obtained from the effluent material.[9]

The disadvantage of the Jackson-Pratt system is that it is bulkier than a simple rubber or a Hemovac drain. However, the flat-shaped drain can be brought out through the incision line while maintaining an airtight seal around it. This avoids making a separate puncture wound for the drain, which is necessary when the Hemovac system is used. Bringing simple drains out through incision lines increases the likelihood of postoperative infection,[15] but this may not hold true for suction drains.

A comparative cost survey of representative drains was done in January 1982 at our hospital. The Penrose drains cost 23 cents each. The He-

movac system, only available as a set with a suction reservoir, costs $18 to $21 per set, depending upon tubing size. The components of the Jackson-Pratt system can be purchased separately, the drains costing $11.55 each (or $11.85, depending on shape) and the 100-cc suction reservoirs $11.85.

We have used the Jackson-Pratt system to drain and to irrigate deep spaces in serious maxillofacial infections and suppurative osteomyelitis of the mandible. We have also used it to apply suction to wounds having the potential for dead space and hematoma formation, such as salivary gland or tumor resections, or after bone grafting to the mandible. Based on our clinical experience, the Jackson-Pratt drainage system has been the most effective and versatile type of drain we have used.

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